| Applic | cants: | Monaci, et al. | | |
|------------------|--------|--|-----------------------|--|
| Serial Filed: | | To Be Assigned | Art Unit: _ Examiner: | |
| For: | | JS MONKEY HER2/NEU, NUCLEOTIDES DING SAME, AND USES THEREOF | | |

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- 4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

| STRESS MAL CENTIFICATE |
|--|
| BATE OF DEPOSIT 7-1-05 |
| EDPRESS MAIL NO. EL98960386545 |
| EPRESS MAIL NO. |
| THEREDA MEDITEA INDI INICIANCES CHOCKION IN |
| BEING DEPOSITED WITH THE UNITED STATES POSTAL |
| BEDIANCE AS EXPORTES MAIN THIS UPPICE IN ADDRESSEE |
| ON THE AROVE DATE IN AN ENVELUES ADDRESSED IN |
| COMMISSIONER FOR PATENTS, R.G. DUX 1436 |
| AI FYANDRIA YERGINA ZULI-1434 |
| |
| |
| DATE 7-14-09 |
| |

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

| | MERC | K & CO., INC. |
|----|------|---------------|
| Ву | /_ | Date |

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

| | RELATED APPLICATION | | | | | |
|---------------------|---------------------|------------|--|--|--|--|
| U. S. SERIAL NUMBER | FILING DATE | MERCK CASE | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| If th | is is inconvenient, additional copies will be submitted upon reques | t. | |
|--------------|--|---|-------------------|
| | | | |
| (| 6. In accordance with 37 C.F.R. 1.97, (check one) | | |
| \checkmark | the attached information is filed within three months of the filing da | ate of the captioned case. | |
| | the attached information is filed more than three months after the Office Action on the merits. | filing date but prior to the m | ailing of a first |
| | the attached information is being filed more than three months after Office Action on the merits, but before the mailing date of a Final Account No. 13 | Action or Notice of Allowand | ce. The enclosed |
| | 1.17(p). the undersigned certifies that each item of information contained i cited in any communication from a foreign patent office in a count months prior to the filing of this Statement. | | |
| | the undersigned certifies that no item of information contained in to a communication from a foreign patent office in a counterpart fore person signing the certification after making reasonable inquiry, w C.F.R. 1.56(c) more than three months prior to the filing of this Sta | ign application, and, to the as known to any individual | knowledge of the |
| | | Respectfully submitted, | |
| | | By: Alysia A. Finnegan | |
| | | Attorney For Appl | licant(s) |
| | | Reg. No. 48,878 | iicani(3) |
| | | MERCK & CO., INC. | · |
| | | Patent Dept., RY60-30 | |
| | | P.O. Box 2000 | 7 |
| | | Rahway, N.J. 07065-0907 (732)594-2583 | 1 |
| | | Date: 7/1/05 | |
| | | Date | |

Approved for use through 7/31/2006. OMB 0651-0031
SUBSTITUTE for PTO/SB/08A (08-03), Information Disclosure Statement by Applicant
Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

| Sı | ubstitute for form 1449A/PTO | 1 | | COMPLIE F KNOWN | | | |
|-------|------------------------------|------|-----------|------------------------|-------------------------|--|--|
| | NFORMATION 1 | DIS | CLOSURE | Application Number | To Be Assigned 10/54127 | | |
| c | TATEMENT BY | A D | DI ICANT | Filing Date | | | |
| 3 | TATEMENT DI | AI. | FLICANI | First Named Inventor | Monaci, et al. | | |
| | | | | Group Art Unit | | | |
| | (use as many sheets | as n | ecessary) | Examiner Name | | | |
| Sheet | 1 | of | 3 | Attorney Docket Number | ITR0043YP | | |

| U.S. PATENT DOCUMENTS | | | | | | | | |
|-----------------------|-------------|-----------------------------|----------------------------|---|--|--|--|--|
| Examiner Initials* | Cite No. | U.S. Patent Document Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | | | |
| | A | 5,846,538 | | Cheever, et al. | 12/08/1998 | | | |
| | В | 5,869,445 | | Cheever, et al. | 02/09/1999 | | | |
| | С | 6,127,344 | | Amici, et al. | 10/03/2000 | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | | |
|--------------------------|--------|------------------------|----------------------------|--|--|--|--|--|--|
| | | Foreign Patent Documen | t | | Date of Publication of | | | | |
| Cite No. | Office | Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Cited Document MM-DD-YYYY | | | | |
| D | PCT | WO 02/22080 A3 | | Merck & Co., Inc. | 03/21/2002 | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | , - | | • | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | No. Office | Cite No. Office Number | Cite No. Office Number Kind Code (if known) | Cite No. Office Number Kind Code (if known) Name of Patentee or Applicant of Cited Document | | | | |

| | Examiner Signature | | Date Considered | |
|--|-----------------------|--|--------------------|--|
|--|-----------------------|--|--------------------|--|

JC14 Rec'd PCT/PTO 0 1 JUL 2005 Approved for use through 7/31/2006. OMB 0651-0031 SUBSTITUTE for PTO/SB/08A (08-03), Information Disclosure Statement by Applicant Patent and Trademork Office, ILS DEPARTMENT OF COMMISSION.

| | | | | Patent and Trademark Off | ice; U.S DEPARTMENT OF COMMERCE |
|-----------------------------|-------------|-----------------|--|--|--|
| betitute for form 1440B/DTO | | | (| COMPLE F KI | NOWN |
| | DIS | SLOSURE | Application Number | To Be Assigned | 10/54127 |
| TATEMENT DV | A DI | DI ICANT | Filing Date | | |
| TATEMENT DI | AI | LICANI | First Named Inventor | Monaci, et al. | |
| | | | Group Art Unit | | |
| (use as many sneets | as ne | ecessary) | Examiner Name | | |
| 2 | of | 3 | Attorney Docket Number | ITR0043YP | |
| | TATEMENT BY | NFORMATION DIST | TATEMENT BY APPLICANT (use as many sheets as necessary) | Application Number Filing Date First Named Inventor (use as many sheets as necessary) Figure 14498/PTO Application Number Filing Date First Named Inventor Group Art Unit Examiner Name | TATEMENT BY APPLICANT (use as many sheets as necessary) COMPLE F Kitch Application Number To Be Assigned Filing Date First Named Inventor Monaci, et al. Group Art Unit Examiner Name |

| | | NON PATENT LITERATURE DOCUMENTS |
|-----------------------|-------------|--|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. |
| | E | Bargmann, et al., "The neu oncogene encodes an epidermal growth factor receptor-related protein", Nature, Vol. 319, 16 January 1986, pp. 226-230. |
| | F | Chartier, et al., "Efficient Generation of Recombinant Adenovirus Vectors by Homologous Recombination in Escherichia coli", J. of Virology, Vol. 70, No. 7, July 1996, pp. 4805-4810. |
| | G | Cheever, et al., "Immunity to Oncogenic Proteins", Immunological Reviews, No. 145, 1995, pp. 33-59. |
| | Н | Coussens, et al., "Tyrosine Kinase Receptor with Extensive Homology to EGF Receptor Shares Chromosomal Location with neu Oncogene", Science, Vol. 230, 6 December 1985, pp. 1132-1139. |
| | I | Disis, et al., "Oncogenic proteins as tumor antigens", Current Opinion in Immunology, Vol. 8, 1996, pp. 637-642. |
| | J | Disis, et al., "HER-2/neu Protein: A Target for Antigen-Specific Immunotherapy of Human Cancer", Anvances in Cancer Research, Vol. 71, pp. 343-371, 1997. |
| | K | Disis, et al., "Generation of T-Cell Immunity to the HER-2/neu Protein After Active Immunization With HER-2/neu Peptide-Based Vaccines", J. of Clin. Oncol., Vol. 20, No. 11, pp. 2624-2632, 2002. |
| | L | Disis, et al., "Cancer Vaccines Targeting the Her2/neu Oncogenic Protein", Seminars in Oncology, Vol. 28, No. 6, Suppl.18, pp. 12-20, December 2001. |
| | М | Foy, et al., "Vaccination with HER-2/neu DNA or protein subunits protects against growth of a HER-2/neu-expressing murine tumor", Vaccine, Vol. 19, pp. 2598-2606, 2001. |
| | N | King, et al., "Amplification of a Novel v-erbB-Related Gene in a Human Mammary Carcinoma", Science, Vol. 229, pp. 974-976, 1985. |
| | 0 | Lohrisch, et al., "An Overview of HER2", Seminars in Oncology, Vol. 28, No. 6, Suppl 19, December 2001, pp. 3-11. |
| - | P | Montgomery, et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination:Optimization of DNA Vectors", DNA and Cell Biology, Vol. 13, No. 9, 777-792, 1993. |
| | Q | Press, et al., "Expression of the HER-2/neu proto-oncogene in normal human adult and fetal tissues", Oncogene, Vol. 5, pp. 953-962, 1990. |
| | R | Shih, et al., "Transforming genes of carcinomas and neuroblastomas introduced into mouse fibroblasts", Nature, Vol. 290, 19 March 1981, pp. 261-264. |
| | s | Shiver, et al., "Cytotoxic T Lymphocyte and Helper T Cell Responses following HIV Polynucleotide Vaccination", Annals New York Academy of Sciences, Vol. 772, pp. 198-208, 1996. |

| Examiner Date | |
|----------------------|--|
| Signature Considered | |

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc., 09/05/2003

| Su | Substitute for form 1449B/PTO | | | COMPLE | | |
|--|-------------------------------|----|---|------------------------|----------------|----------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | To Be Assigned | 10/54127 |
| | | | | Filing Date | : | |
| | | | | First Named Inventor | Monaci, et al. | |
| | | | | Group Art Unit | | |
| | | | | Examiner Name | | |
| Sheet | 3 | of | 3 | Attorney Docket Number | ITR0043YP | |

| NON PATENT LITERATURE DOCUMENTS | | | | | | | | |
|---------------------------------|-------------|--|--|--|--|--|--|--|
| Examiner Initials* | Cite No. | Include name of the author, title, date, page(s), volume-issue number(s) and place of publication. | | | | | | |
| | Т | Slamon, et al., "Studies of the HER-2/neu Proto-oncogene in Human Breast and Ovarian Cancer", Science, Vol. 244, pp. 707-712, May 12, 1989. | | | | | | |
| | ប | Slichenmyer, et al., "Anticancer Therapy Targeting the ErbB Family of Receptor Tyrosine Kinases", Seminars in Oncology, Vol. 28, No. 5, Suppl. 16, October 2001, p. 67-79. | | | | | | |
| | v | Yarden, Y. "Biology of HER2 and Its Importance in Breast Cancer", Oncology, Vol. 61 (Suppl 2), 2001, pp. 1-13. | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| : | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

| Examiner Signature | Date Considered | · |
|-----------------------|--------------------|---|